

Food Facility Registration and Prior Notice

Anthony C. Taube, Director, Division of Food Defense Targeting

(Sousan Altaie): All right, I'd like to introduce to you Mr. Taube. He's the Director of the Division of Food Defense Targeting and he's very savvy in showing you how you could go do a prior notice easily on the Web page. So please welcome him. Thank you.

(Tony Taube): Good morning, everybody. Let me make sure. Can everyone hear? Okay? In the back? All right. Thank you. I want to thank the Office of International Programs for inviting me out to talk a little bit about food facility registration and their prior notice of imported foods, Captain Veneziano mentioned a couple times during his presentation our process related to food defense and specifically related to the food facility registration requirement and the prior notice of imported foods.

So I wanted to talk a little bit about how to navigate on our Web site to obtain additional information on both of those and then give you a little information on both registration and prior notice as we go along. So as you can see, right now we're on the FDA.gov Web site and the primary link you want to click on to get to the - both the food facility registration and the prior notice of imported foods is that food tab.

So right here on the commodity tab, you see the food, so I'm going to click on that particular tab and that'll take me to the food portion of the FDA Web site. And before it comes up, I will let you know that periodically the site of the next link I'm going to show you change. I think they do it to throw us off or just like they do it at the stores when they rotate where you

find your favorite cereal or something, they move it somewhere else to draw your attention to those things as well.

So, they do that periodically on our Web site, but right now the two links that I want to show you in popular topics, we are one of the most popular topics, is the prior notice of imported foods over here on the right. And then if you scroll down a little bit under spotlight, there's the section on registration of food facilities.

And I'm going to go ahead and go to the registration of food facilities first. If I click on that, that'll take me to the registration of food facilities Web site or page. And there's a lot of good information on this particular page. Domenic mentioned that, you know, the food facility registration requirement came out of the Bioterrorism Act of 2002.

At that time, the only food facilities worldwide that had to register with FDA were low-acid canned food firms and infant formula firms, and that was probably less than 1000 firms worldwide. With the Bioterrorism Act requirement, any food facility that prepares, packs, or holds food for intended consumption in the United States or transits through the United States -- actually it's only just for the intended consumption, let me go back -- has to register with FDA.

So that opened it up to just thousands and thousands of food facilities who want to bring their products into the United States and the requirement to register with FDA. And at that time it was a one-time registration. You registered and as long as your operation didn't change, you never had to go back in and re-register.

Well, the Food Safety Modernization Act changed that and now requires a biennial re-registration and it happens or it occurs in the even numbered years. So last year 2012 was the first biennial re-registration and the actual period, the normal period for registration or biennial update is October 1 through December 31 of those even years.

The first period, our Web site wasn't quite ready. Where did you hear that before? And we actually delayed the - but we delayed. We delayed the implementation of the biennial re-registration for about 21 days and I think it opened up on October 21 or 22 of 2012. And because we were delayed, we actually extended it into the end of January 2013. But I would expect 2014, so next - this coming year that biennial update to stick to the schedule October 1 through the end of the year, 12/31.

So, what does FSMA also -- the Food Safety Modernization Act -- also require? It requires - well, we updated the registration process by clarifying some of the information about facilities, about what you do at that facility, what products are manufactured or held at that facility, and it also requires facilities to acknowledge that by registering and by having their products in the United States, they are subject to FDA inspection and you're basically acknowledging that - you're acknowledging that you'll permit FDA to inspect your facility.

And that's really important because if something Domenic brought up during his presentation about persons registering companies where they really - the company itself may have had no intent for their product to ever be consumed in the United States, and we are seeing some of that occurring, Domenic mentioned the gray market where, you know, someone buys a product in a foreign country and they are just a distributor and then they sell it to the United States and then it's imported, and that

manufacturer has no idea that their product is now entering the United States or attempting to enter the United States.

And they never had any intent so they don't want to be inspected by FDA, they don't want to register, and that product should be held at the border and refused entry under 801(l), which is the registration requirement. So, what is happening in some cases is you have importers registering those foreign facilities on behalf of the manufacturer.

And I bring that up because and when I brought up a search on the actual regulation for registration, which is 21 CFR Part 1 Subpart H. I'm going to do a quick search so I can bring up the language. And I always use the Cornell Law because it's easy to navigate. But Subpart H of 21 CFR Part 1 is the registration of food facilities under who must register, it describes who is authorized.

So, it says, "You," -- and you is defined as the owner or operator agent in charge of that facility -- "must register." But it also gives under C that you as the owner and operator in charge may authorize an individual to register your facility on your behalf. With that comes some responsible relationship between the person you authorize and you, the owner/operator/agent in charge, so it shouldn't be some third party importer who you have no idea who they are, you've never had any kind of business dealings with them. They shouldn't be registering you and committing your facility to FDA inspection.

And our agency, we're working with our Center for Food Safety and Applied Nutrition to look at some of the registrations where we think these third parties are actually registering facilities unbeknownst to the manufacturers themselves.

And again, we're looking to invalidate and have invalidated some of those registrations for that reason. So, it's very important for you to advise your industry folks that, you know, they're the ones that should register or if they want to choose to use someone to register for them, that they have that business relationship and authorize it and recognize that they are also subject to an FDA inspection.

There's businesses out there who are set up to promote to industry that we'll register you for FDA for a price, of course. The beauty of it is registration is free, so any facility could do it on their own for free. And so again, you should also advise your industry folks that FDA registration is free, you don't have to pay someone to do it but if, you know, you're certain - they're certainly welcome to do so under the regulation under §1.225 (c) is to have that business relationship.

So, the first area you're going to want to go into if you're working to register a facility is on the left hand side you'll see this link to user guides for online registration, and I really recommend going through this first to have all the information at your fingertips when you go to register a facility. They're under the second link here in the middle of the page, registration for facility step-by-step instructions.

If you click on that link, it actually goes through, shows you the screens, what they look like, and step by step tells you what you need to have in front of you when you register a facility. So you can see the first thing it asks what type of registration and the type by type it means is it a domestic facility or is it a foreign facility?

So, all of this information, if you scroll down -- and it goes down quite a ways -- shows you and tells you what each field you're going to need to fill out and what information is required in those fields. So, this is really a good tutorial on how to register and what you're going to need once you enter the system.

I will go down to - I mentioned the food products. So here it gives the opportunity to tell us what kind of food and there's - you can scroll down in here what kind of food you're manufacturing and then what your facility does. Are you a warehouse holding facility? Are you a acidified low-acid canned food manufacturer? And I understand it's really hard to read up here, it's a little blurry. I have glasses and I can barely read it.

But you can then check each of the boxes, if I'm a manufacturer/processor I can check this box, which says that I'm a manufacturer of alcoholic beverages, for instance. So you kind of just go and check which products and what kind of process your facility does with that kind of food.

But I want to also go down to the section 12. This is that inspection statement. So, by checking or selecting this box and you have to, to get a registration, you acknowledge that FDA will be permitted to inspect a facility at a time and the manner permitted by the FD&C Act. So, that's where if you don't you have a business relationship with a company who is registering your facility, they have no business making that commitment to your facility.

So again, you want to advise the folks you guys deal with that again, it's free and they're going to want to make their own registration or, again, have their authorized agent do it but with the understanding that they're giving them approval to do that.

And then Section 13 is that certification statement that you have that business relationship, that if you're not the firm itself, if you're not the owner/operator/agent in charge, that you have authorization to act for that owner, agent, or operator.

And it also gives that warning about the 18 US Code 1001, and I think both sites or both this and the prior notice have that warning that if you're giving false information to the government, you're giving - you're actually committing an 18 US Code violation, which is a felony.

So, you know, again, you want to make sure the information is accurate and again, that you have authority to do so. So, like I said, I only bring this up really because we've had this rash of these importers and third parties just registering companies willy nilly as if it was just an administrator filling out a piece of paper and they shouldn't be doing so unless they have that business relationship.

So again, this is that step-by-step instructions are really good place to start if you're going to register a facility. We're going to jump back. You can see there's information about the biennial registration renewal in this particular field and then additional capabilities in the FFRM, which is the Food Facility Registration Module.

Then you can see that there's a summary of fields in the food facility registration and then important there is a contact for help with food facility registration, that's our "FURLS", or our FDA Industry Systems Help Desk. There's a phone number, two different phone numbers, an 800 number and a 301 number, and there's a Web address where you can send

emails to that staff to answer questions with respect to food facility registrations.

They are the staff that can also help you with accounts, so if you have an account to register because just like everything else you have to create an account first and then you can go register a facility. So, they can help you with creating your account or if you have problems logging in, they can help troubleshoot why you're having trouble logging into your account, so this is a great resource to have as well and it's at your fingertips here on the Web site.

Want to point a couple other things out before we log in and show you how you get to the registration. There's guidance down here on the right hand column, there's guidance for industry related to food facility registration. I believe we're in the process of updating some of this guidance as it was linked to the Food Safety Modernization Act, so this is a good place to go as guidance is made new.

Here's a link on registration under Food Safety Modernization Act. And then compliance policy guide for FDA staff when it comes to enforcement. And again, that's a good link or a good document to read as well. So, to log in, to register a facility it's just log in, create an account. This is our FDA Industry Systems page and this is the same page you'll see in a minute when we go to do a prior notice that you would log in to file a prior notice.

So, my particular account has the ability to do both. I'm going to log in and put my super-secret password. And why did it give me that error? Because "I didn't understand." So you have to click "I understand" and I make this mistake all the time. You have to understand that your 18 US

Code, that thing I just mentioned, so I didn't click the "I understand." So hopefully it'll work this time. All right.

Okay, it liked it that time. So, once you get into this account management, you can see this particular account was signed up to do both registrations and prior notices. So, we're going to use it now, I'm just going to show you real quick how you would go in. So once I'm in my account, tells me my account name, I can go into the food facility registration, and then it gives me a number of links.

This is now in our FFRM or Food Facility Registration Module. I can register a food facility, a new facility, I can update an existing food facility, maybe we move two doors down and our address changed, that would require you to go in and make an update to your registration outside of that biennial requirement.

You can cancel, maybe your firm went out of business or you sold it, you want to cancel your registration because you didn't want to convey that registration number, you can cancel registration. You can search for one of your registrations. You can't search for any. As Domenic mentioned earlier, some of this firm information we're required by the law to keep confidential and so if you - you can't call up the FURLS help desk and say, you know, "What's the registration number for firm XYZ in Japan?" We're not allowed to give that kind of information out.

We can link a registration and then confirm. I'm not even sure what that means. But again, most people would go in to register, and I will add during the biennial, there is a link to update the biennial update because some of the folks in the first round went in and created a new one and thought they were doing an update and some used the update function and

what they really wanted to do was do the biennial update so you're really going to want to advise your folks to use the right button that it's abundantly clear, it says biennial registration update.

So we're pretending like we're going to register a new facility. And again, it just goes through step by step just like most Web sites, you know, this is going to be a foreign, are you a new owner of a previously... no, we're going to say no, and we hit continue, it takes us to step two. And this is where, again, if you have all the information, if you are the owner/operator in charge, you've probably got all the information right up in your head and, you know, you can do this with probably 10/15 minutes.

If you're an authorized agent to do it and you have all the information, you know, it might take you 30 minutes. If you don't have the information, that's where you're, you know, you're going to get stuck at certain points in this registration process. But it just goes step by step and asks you to enter all the information and I'm not going to go through it because it's pretty self-explanatory. I will note that there's starred (*) fields, those are mandatory fields, so it's going to not let you move forward until you have each and every one of those starred (*) fields filled out.

So we are actually going to go back to our FFRM home and, again, that's essentially the process of registering a facility and I always say, "Why pay someone \$500?" And some of them charge it annually to register your facility when it's free. And it's not that difficult of facilities to do on their own, so - and quite frankly we like it that way because we feel like we're getting the best information if someone from the facility themselves is actually doing the registration.

Now we are going to go back to the FURLS home. So getting out of that particular site can be a little tricky. I had to click on “FURLS Home”- there was no - back button doesn't work, you have to go to FURLS Home, which takes you back to your account. I will note that you can edit or change your password or edit your account profile from this particular site as well and, again, it's a good way to go in and manage your own account if you need to add things to it.

And FDA is really using this as a home. I don't know that if ITACS that Domenic mentioned earlier will use this account management system but I think it's a good chance that they will because this is an existing account management system FDA has and you can see if you do medical devices you can set up your account to do medical device registration and export certification for devices, so depending on what kind of business you are, this is your account home right now for FDA systems.

So right now we're going to log out and go back to the FDA Web site to finish our... I think the “back” won't work now, so I'm going to go back to the home page here and we'll go back to food, and we're going to go to one of the most popular topics, which is the prior notice of imported foods.

So Domenic mentioned some of the time frames. Are you guys familiar with prior notice at all? Show of hands. No? Okay. So I'll give you the quick background behind prior notice. Before prior notice of imported foods just came out of the Bioterrorism Act, and the Bioterrorism Act that you may be familiar with is a huge act, it has many, many requirements in it.

But one section Title 3 relates to protecting the US food and drug supply and a couple of new requirements within Title 3 were the prior notice of imported foods and the previously mentioned registration of food facilities.

Before the prior notice of imported foods, FDA often got notified of food shipments coming into the country long after the food was already in the country, and you can see that that's problematic in protecting the food and drug supply because foods would come in, you know, it could be 500 miles in the country under bond before FDA even knew it existed.

And, you know, with the threat of terrorism and unsafe products, you know, Congress said, "That's not - that's something that doesn't make sense." FDA needs to be notified of those shipments before they arrive in the country so that we have the opportunity to target inspections of those shipments at the port of arrival to protect the US food supply.

And so with prior notice, we get that notification within, depending on the mode of transportation, two, four, or eight hours before that food shipment arrives into the country. So for land by road shipments, so truck-type shipments on land borders it's two hours before arrival, and that's minimum time. They can submit it - it can be submitted up to 30 days in advance of arrival, but that's the minimum time frame is two hours before arrival.

For air and rail the minimum time is four hours and for sea shipments the minimum time is eight hours before arrival. And we are committed to having the answer for US Customs or our border staff whether or not we want to examine that shipment upon arrival.

So my staff is there 24/7, 365 days a year receiving prior notices, making those decisions so that the Customs and Border Protection officers and the FDA officers at the port know if we need to inspect those goods from a food defense perspective at arrival.

And if it can move into the country and move to the admissibility side of the house that Domenic mentioned earlier, then it can move in under that process. So again, you know, the process is twofold. We don't do the same thing the field staff in that admissibility process that Domenic talked about earlier. My folks look at the food defense side of the house. We're looking for intentional - effectively looking at signs that lead to intentional or could lead to the food was intentionally adulterated or signs that the shipment may be linked to terrorism.

So, those are the kind of things we're looking for. So that's prior notice of imported foods in a nutshell. And what I'm going to show you now is what - to see the information surrounding prior notice of imported foods, what are our policies and how to file prior notices. And I'm going to show you actually one of - only one of the two ways.

The way I'm going to show you is through our FDA Web site, our prior notice system interface, which again is free, it's a way anyone can submit a prior notice for a food shipment.

Again, they're going to have to have the information about the food shipment to file the prior notice but they can file it on their own for free. The other option is to use a Customs broker, which is probably 80% of the way imported food and imports come into the country probably in most other areas it's near 100% go through a Customs house broker.

That is a licensed broker by US Customs and Border Protection who are licensed to file all the paperwork and all the information with Customs to make sure that that shipment can legally move into the country. Those licensed brokers can also file prior notice as well and, you know, some companies, commercial shipments, they just prefer to give the entire package to that broker to say, “Do all of the things you need to do to file for this shipment coming into the country,” and that would include the prior notice.

This system is available largely for informal shipments, so low-value shipments or, like, land where I came from the Detroit office of FDA, where you can almost throw a rock into Canada across the Detroit River, and there's a lot of informal shipments that flow across that border and mean informal is less than \$2500 worth of goods. So, stuff manufactured in Canada coming over the border to be sold in Michigan and the surrounding areas and Customs says under value of \$2500 there's no formal entry that has to be filed.

That doesn't negate the requirement for prior notice. Prior notice still has to be filed for those shipments and so this system allows companies who are in that kind of business to file prior notice. Customs sometimes does force low-value shipments to file formal entry but it's usually based on violative histories or problematic histories of, you know, the importer or the supplier source, but there are policies related to low-value shipments.

So, the Prior Notice System Interface about 16% to 20% of those prior notices filed come through this system. The information is the same regardless of if you go through a Customs house broker or the Prior Notice System Interface, but the actual process is a little different and I'm going to take you through that process.

But I do want to show you again we have a step-by-step instructions so that if you haven't done it before, you can do that first, go through those instructions so you understand what are the - what's the information you're going to need prior to filing a prior notice and there's also further on down you can click the information on the final rule related to prior notice. The Food Safety Modernization Act modified the requirements for prior notice one small area.

The Act said that now with prior notice if the food being imported was ever refused entry by any other country, you have to tell us what country that was. They don't have to tell us why, but they have to tell us the country that refused that particular food. And by that particular food, I mean the food in that shipment, not this commodity was once refused entry by Germany 10 years ago.

No, it's the food in - that's coming into the United States, this particular shipment, if it was refused entry, they have to tell us what country refused that food. And of course, what are we going to ask? Why?

So, typically that's going to be the next question coming to the importer or the filer before we allow it to move into our country. But even US goods, so if some food that's manufactured in the United States goes over and is refused by Japan and it comes back into the United States, it has to have prior notice and they have to tell us that Japan refused that food when they file the prior notice.

So, it's a small change but it did require us to go through the rulemaking process again and add that requirement into the rule and the prior notice final rule became effective again May of 2013 so it's about six months, the

final rule became effective again. The actual rule has been in place. We're coming up on our 10th year anniversary of the prior notice of imported food requirement, it was December 12, 2003, when this process started, so we've been going at this for about 10 years.

The other two important guidance documents that are helpful are questions and answers. This is commonly-asked questions, so if you have something that you have a question about prior notice is a good first stop to see if that question has been asked and what FDA's policy is on that particular issue.

This particular guidance document, these question and answers, is under revision because of the Food Safety Modernization Act change and that refusal country, and we hope to get that out, our goal was to get it out by the end of the calendar year 2013.

It's under final review. I can't predict whether it's going to come out by the end of the calendar year but I would expect if not by the end of the calendar year in the first couple of months in 2014.

The other good piece is the Compliance Policy Guide, which I will click on, which talks about some enforcement discretion areas with respect to prior notice. And I bring this up because one of the questions I heard asked earlier about samples and I think the question more related to trade samples or for show, a trade show, and as Domenic correctly pointed out, those would still require prior notice.

Samples going to a laboratory for testing may not. So if you're, you know, someone sending one can of soup in to a laboratory for analytical testing, we're generally not going to require prior notice for that particular shipment because it's not intended to be consumed, it's intended for

laboratory analysis. But this talks about some of those - some discretionary areas.

Let's see, what's another one? Seeds for cultivation are mentioned in here. What's another one we get common questions on? Here's food for quality assurance research and testing is under B, and then food for noncommercial purposes with a noncommercial shipper irrespective of type of carrier. So, person-to-person shipments, so if I send something to a family member.

And again, it's I'm sending it, it's not a business, I'm not a business and they're not a business, I'm sending a person-to-person shipment, will generally not require prior notice. It doesn't mean it's not required, and that's a distinction. It's just an enforcement discretionary, we're not going to enforce it if it's a person-to-person shipment.

But if you have a mail order business or if someone goes on Amazon and orders it or eBay or whatever or company's Web site and the company ships it to a person, that's a commercial shipment, prior notice is required, and we don't waive - we don't exercise discretion, I should say, in those cases, so prior notice would be required.

So again, this is a good policy document. This has been updated periodically so again, if you read it once, you know, it's good to come here periodically and see if the policy has changed.

All right. So I'm going to - how are we doing on time Sousan? Okay. All right. Doing good. So, I'm going to go ahead and log into our account again. Hopefully I can get it right the first time. So this, I'm going to go ahead and click on the prior notice of imported foods. And that takes us

into, you can see the name of this system is the Prior Notice System Interface or PNSY, you might hear that term, PNSY, that's just the acronym, fancy way of saying the acronym.

So again, there's, you can use a number of links, you can use the Get Started, which gives you an overview. There's a link for new features. And this particular system is updated periodically but typically it's only when there's either a bug identified and/or a new requirement, like we had to modify it for that Food Safety Modernization Act change for refusal country, but other than those changes it's pretty static because the prior notice rule, the information that's required hasn't changed all that much and this has been a pretty stable system for the last several years.

Typically if you're going to create a new prior notice for a shipment you're going to use the click the "Create New Web Entry." I know that isn't really necessarily intuitive but that's effectively - again, these helpful hints here are invaluable if you actually go read them but, you know, if you're like anybody, I do the same thing, I'm, you know, you just, you wildly click, you do things without reading all the fine details of, but this will really tell you - this is where you start if you want to file a new shipment.

If you're going to - maybe you started one and you need to finish filing the prior notice, that's where you might want to find an existing Web entry or find an existing prior notice that you started and didn't finish. So, we'll go ahead and click create new Web entry, and again, it's going to take us step by step. And I'm going to actually go through this process.

So, the first thing it asks us for is the entry type. And if you need help on entry types, you hover over the need help and it's going to tell you what each of those entry types mean.

So in this case, we're going to choose consumption, almost all the shipments that come in, you know, it's a probably good 80% that come in are actually consumption entries. That means they are intended to be consumed within the United States. Obviously, there's more specific things like baggage or mail, that means it's coming in either through someone's baggage or through the mail.

There's transportation and exportation. Because for prior notice, even food transiting the United States has to have prior notice before it crosses our border. So if something is manufactured in Mexico, for example, but its destination is Canada but it's going to be trucked through the United States, they have to file prior notice to actually move that food through the country.

So they would choose transportation and exportation. But like I said, most of the shipments would be either consumption or consumption express courier, which is if it was coming in through one of the express couriers like FedEx or UPS or something like that. We're going to actually use consumption so we select that off the list of values and then we click next.

The next thing it's going to ask us for is entry information and it asks us for an entry identifier. If you are not a Customs broker or you're not working with a Customs broker, you're probably not going to have an entry identifier. The nice part is if you don't have one, you can click this not known and the system will generate for you an entry identifier. We're real nice, like that, you know. We don't stress you out. If you don't know it, we'll create one for you.

It's a joke because that's about the only thing wrong within the system. So, but we will generate one if you don't have one. If you're working with a

filer, maybe they're going to do the rest of the shipment documentation for you.

You can ask them, “Does this shipment have an entry identifier.” And if they give it to you, you can actually enter it in to this field and entry identifiers are set up with a three-digit filer code, each filer license customs filer has a three-digit code and then the rest of the digits on the code or the entry identifier are the entry numbers.

So, in our entry identifiers are set up similar but you'll see a pound, pound, pound in front instead of the filer code if it's a consumption entry or any of the others other than mail, which will show up as plus, plus, plus as an entry identifier. So, we're going to then select how many prior notices. In this case we're just going to select one.

Prior notices are dependent on the food coming in, in the shipment. So each food that has a unique manufacturer FDA product code or package size requires a separate prior notice. So for instance, if you're bringing in canned tuna and you have six-ounce cans, eight-ounce cans, and 12-ounce cans, they're all manufactured by the same company and they all have the same FDA product code, but it's because of three sizes, that's three prior notices.

If you have waffles and soup, that's two prior notices. If you have strawberry waffles, blueberry waffles, and cinnamon waffles, how many is that? Anyone want to guess? I heard one. I heard two. I had cinnamon, blueberry, and strawberry waffles. All manufactured by the same company, all 16-ounce packages.

The actual answer is one. A lot of people say three because I have three flavors. The difference here is FDA only has one product code for waffles, so regardless of flavor, we only have one waffle product code. So technically speaking you only have to file one prior notice. But in this case, we always encourage folks you can file one each for the different flavors because if FDA decides they want to sample just the strawberry, then - and analyze it and release the other two, you can release the other flavors without holding it.

If you file it all under one, you're probably going to get stuck holding all your waffles. So, again, you know, under the rule prior notice is required if you have unique manufacturer, a package size, and/or an FDA product code. I'm going to make it simple for us, we're going to just do one.

So we'll enter one there, go down to the next section, which is the port of arrival. In this case I'm going to say it's going to come in through Detroit, so I'm going to select Michigan and then I'm going to ask if I don't know the port code, I'm going to ask to find the port code. I use the list of values for all the ports in Michigan and I can select Detroit, which is 3801, and then click next, and it actually entered the port code for Detroit 3801.

Next thing it's asking me for is the anticipated arrival date, and again, this is what it says, anticipated arrival. It doesn't have to be exact. So, I think it's coming in I was told by the shipper it's going to come in on Friday so I'm going to put 12/6, and then and I'm told it's going to be there by 9:00 am so I'm going to select 900 hours.

So again, just anticipated, doesn't mean you have to be exact when it comes through anticipated date and time of arrival. The one thing it will bounce out is if I say it's, you know, 60 days from now, it won't let me do

that because I can only file at the max for Prior Notice System Interface 15 days in advance. So it will only let me put a date 15 days from the current date.

All right. So then I go to submitter. Who can submit a prior notice? Anyone care to guess or read the regulation? Stay up late and read prior notice regulation? Anyone can submit a prior notice. Anyone with the information is allowed to submit prior notice. In this case, I'm the submitter and I'm also what's called the transmitter. I'm the one punching the keys here so I can actually say that I'm the submitter for this Web entry, I can click yes, and it's going to take the information from my account as the transmitter and copy it into the submitter field.

If I'm not the submitter, I click no and then I can go to the enter submitter information and enter my name, company name, if applicable, and address. But in this case I'm just going to say "Yes", and I'm the submitter as well as being the transmitter, the person clicking the button. Now, for importer, is the importer the same as the submitter? Might be but in often cases no.

So in this case I'm going to enter the importer, and again, and I didn't show you the other one because the field pretty much looks the same and I can enter the importer information so I'm going to enter Tony's Imports, date, and the zip code.

Now, the field at the top, food facility registration number, if Tony's Imports is registered and I know the registration number, I can enter it here. It's not a required field so I can leave it blank. The other thing you'll see there's another thing, add to my favorite list, maybe I do prior notices all the time for Tony's Imports and I want to add it to my favorite lists.

Well, I can only add it to my favorite list if I have their registration number.

So, in this case I'm not going to be able to because I don't have Tony's Imports' registration number so I'm just going to hit save here and then it's going to enter Tony's Imports in my importer section of my prior notice or Web entry in this case.

And then the last thing on the Web entry it asked me for is the "Carrier." It's going to ask me first for the "Mode of Transportation" so I'm going to say land, by truck, and then I'm going to enter the carrier information on the next page. And the first thing it's going to ask me for is the SCAC code, which is the Standard Carrier Alpha Code. What if I don't have this but I know it's FedEx Ground, for instance?

I can actually, let's see, I can actually find a code by putting the carrier's name in, do a search, and there's my carrier listed here. So any firm that has a SCAC, and most common carriers have a SCAC, it's probably 95% of shipments come in using a common carrier so they would be able to find them in here, so if you have that information you can find it.

If not, if it's a privately-owned vehicle, you can put the license number, the issuing state or country, province of that license number in these fields, and then go without a carrier name and SCAC code. A "Trip Identifier" is, you know, just like on a flight, a flight has a flight number, you would put that here if a shipping line has this is, you know, trip identifier 456 you would put that here. A lot of truck shipments don't have trip identifiers so I can leave that blank.

And then for a “Bill of Lading,” I would want to put the bill of lading in the documents, bill of ladings all start with, if they're a common carrier, start with that SCAC code and then it's a series of numbers. So I'm just going to make one up and then save that carrier information. So once I have the carrier information entered, I'm ready to go ahead and move to file the actual prior notice for the food that's coming in on the shipment that we just told you about the actual shipping information.

So I'll click “Save,” it takes me to this new screen where then I can create a prior notice. It shows me all the information I just entered as well. So I'll click “Create a Prior Notice” and now it's going to start asking me for information about the food and the shipment. So first is what is the country from which the article is shipped? And we're actually going to say Japan, put in the first letter, it will take me down to the J, there we go.

Next is “FDA Product Code;” Domenic mentioned that ITACS is hopefully soon have the product code builder, PNSI has the product code builder right in it so if I don't know it I can find or do a search. In this case I'm going to say I have soup so I'm going to look up soup. I'm actually going to say I have vegetable soup, and you can see all the different soups that are in. So I'm going to find the best one that fits my particular product and I'm going to say this is actually mixed vegetable soup and it's concentrated so you have to add water to it as a canned soup.

Once I select that, it selects a part of the code for me. All I have to do is build the last two parts, first being the packaging method, so my soup's in a can so it's metal, so I'm going to select the metal E and then the process that applies and that's commercially sterile because it's low acid canned food. The packaging method is what's touching the product, so what is physically touching the product, in this case it's metal.

If it was packaged in plastic, you would choose plastic or flexible plastic, non-flexible plastic, depending on the case. If it was in glass you would choose glass. If it's, like, boxed macaroni and cheese where you have multiple surface, you can choose multiple. But in this case we have metal and our process that the soup is manufactured is commercially sterile. So I select those two, hit the select button, and now it's told me my code is 38BBEE28.

If I know that, I could have typed it right in, and a lot of companies keep those handy so that if they do the same thing over and over they can type them right in. So, I can put in if it's a corrected description, vegetable soup. If you want to put the brand in, you can put that in as well and the common or usual market name for it.

“Production Identifier”, this is like lock codes, so a canned soup typically has some kind of number stamped into the code or onto the lid or jet coded onto the lid. I'm going to enter what I find at the end of that can, Hit save, and then it goes to quantity and packaging, and this particular section can be a little tricky so if you haven't done it before I suggest using the wizard, which kind of graphically tells you that you start with the smallest package, so that's the base unit, in this case a can size. There's so many cans to a carton and so many cartons to a box.

And so the process, this will actually walk you right through it. So I'm going to say we've got a 12-ounce can. I can enter 12 in the quantity and then select ounces in the measure, click next, and then I'm going to say how many cans are in a box, and I'm going to go with 24 as well. Click next and I'll say that there are 12 boxes per case. And then once I do that, I can click finish and you can see it tells me again 12 ounces is the base

unit, 24 boxes, 12 cases per box, and it does a quantity of 3400 total ounces in that shipment.

And click okay. And again, I could have done it without going to the wizard but the wizard kind of walks me through the process in a more easy way. So, if you have experience in the system, it's pretty easy. And the last section on this particular page is the refusal information, has this article been refused entry by any other country? If I say no, which is the default, I don't have to enter a country. If I say yes, then I can click on the particular countries.

And you can actually, if it was refused entry in multiple countries, you can use the control click to select multiples. In this case I'm going to go back to no, and it's going to take those out for me, hopefully. Hit save. Now it took me to the next field and you'll be glad to know this is the last part of filing a prior notice, and that is the facilities associated to that shipment.

So in this case it's asking me first for the manufacturer, it's going to ask me what country that's from. I'm going to say Japan again. And then I can enter the manufacturer. In this case you see food facility registration number is asterisk because it's required. A little bit of a misnomer because if I don't have it, I can use this field down here and I'll talk about that in a minute but I want to enter I'm going to say I got the Tokyo Soup Company.

Does Tokyo have Oak Street? I figure most cities have an Oak Street, at least most cities in the United States. Does Tokyo has zip codes? I don't know. Does anyone know. You can see it's not a mandatory field because not all countries use zip codes, but if you do, again, you can enter it.

So, if I don't have the food facility registration number, I can use either the manufacturer is not required or registration number is not known. If I choose that, I have to put a reason I'm not giving a registration number. And in this case there's a choice called unable to determine registration number of the manufacturer, and that is a perfectly legal way to do it. This is where you get into that tricky part of manufacturers who aren't registered, foods coming in because the registration number is not a required data element.

But we went through a long battle with the rule because originally it was required and we kind of lost out in requiring it as a final element in the final rule and so it's no longer required. We- if we- what we tell this trade is that if you don't give us the registration number it may take us longer to process those shipments and you may not have the answer when it hits the border.

So, again, it behooves those in that supply chain to have those registration numbers where they apply and put those in the prior notices so that they can be processed in a timely manner. But it's legal under the rule to submit it without. It'll also ask us if the manufacturer would be the default for new prior notices for this web entry if we had multiples coming from the same, if we had mushroom soup and tomato soup, we could say yes and then it would copy that information in for us.

In this case we're going to say no. Again, we can't add it to our favorite because we don't have a registration number so we'll just hit save here, and it enters that information for us. For the shipper, I'm going to say that the shipper is the same as the manufacturer so I'm going to enter the country. If I go to shipper, I'm going to say shipper same facility as manufacturer, hit save, and then I don't have to reenter that information.

The owner, I'm going to do the same. The owner is who owns the goods at the time of the shipment and I'm going to say they're still officially owned by the manufacturer. Let's say maybe because maybe the importer hasn't paid for them yet. So it's the same as the owner and then the ultimate company. In this case I'm going to say they're being delivered right to the importer so I can say ultimate company is the same as the importer.

Don't have to waste my time reentering it, hit save, and I've just buzzed through entering all that information. So you can see we do help a little, you don't have to reenter those things multiple times if you've entered it already under one of the other parties.

The last thing on this page is the holding facility. This only has to be entered post-refusal. So if we refuse this for some reason and the shipment has to be held at the border and moved to a holding facility, you would have to come back in and enter a holding facility.

Most prior notices don't have to have a holding facility entered, so I can leave this blank and move on. So once I'm done with that, I can go ahead and submit my prior notice by clicking that button. It's going to summarize all the information I just entered. If I'm cool with it, if I don't have any other edits, I can say yes, submit the prior notice, and it's going to ask me if I want to complete my Web entry so that if I want to enter additional prior notices, I could.

I'm going to say no, that's it. But you can see it's already given me a prior notice confirmation number, and you can tell the nomenclature for the confirmation numbers always start with the last two digits of the year so

we're in 2013 so the first two digits are 13 and then a numeric sequence of numbers for my prior notice confirmation number.

So I'm going to go ahead and hit yes here. I can complete my Web entry and I just submitted a prior notice to the FDA. If I want to print a summary for my records, I can do that by clicking the "Print Summary" button.

For shipments where someone's bringing it over, this is a good way to hand carry something either a truck driver could carry this, present it to Customs at the border. It has a confirmation and a barcode that they can scan so they can easily process the answer or get the answer on FDA's answer on can this shipment move past the border, so this is a useful thing.

This isn't required if, you know, it's being loaded into a container, do you have to have this inside the container? The answer is no. But it is a useful tool for more of those informal-type shipments. So if I want to go back to the home screen and find that existing Web entry I just submitted, I can click on that button and it's going to show me - or actually I'm going to do completed because that's one I just completed, and then search.

I should be able to see the prior notice we just filed. Did anyone get the Web entry number? Is this it here? 3801, probably it right there. No, that's a different one. Oh yes, it's this one then 12/6/2013, right? Isn't that what we said? Here it is, vegetable soup.

So again, if I have this shipment over and over again, I can use this copy function and it will copy all that information into a new shipment and all I have to do is update things like anticipated date of arrival, maybe the quantity, maybe the next shipment isn't quite the same quantity, any

information that changes I have to go back in and update but it does save me the time in retyping it.

The thing you want to warn about copy, using the copy function is you have to go back in and make sure those fields, that change are updated with the new information, but it is for time purposes you cut 75% off if all the rest of the information stays the same, if you have that supply chain constant, you know, you can use existing prior notices to quickly file new ones.

So that's pretty much Prior Notice System Interface in a nutshell. Any questions? Either on prior notice of import of food, food facility registrations, or filing a registration or filing a prior notice? I've done a great job.